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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,678	12/08/2000	Gerardo Byk	ST98009	9996

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/13/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,678

Applicant(s)

BYK ET AL.

Examiner

Richard Schnizer, Ph. D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372. The specification teaches that the compounds according to the present invention belong to the family of cationic lipids. See page 3, lines 10-15. However, the breadth of the claimed genus of compounds far surpasses that of the family of cationic lipids, and none of the independent claims recites any requirement that the recited compounds must be lipidic in nature. In addition the claims are so indefinite as to render it impossible to determine the scope of the claimed subject matter. For example, R1 is defined at page 79, lines 13-17 as a group of general formula (III) for which 'p' and 'q' are integers of "between 0 and 10 inclusive". While the phrase "between 0 and 10" clearly means "from 1-9", and "0 to 10 inclusively clearly means "from 0 to 10", it is utterly unclear what is meant by the phrase "between 0 and 10 inclusive". Also, R' is defined at page 82, lines 10-15 as representing either a group of formula NHR₆R₇, for which R₆ and R₇ may independently represent a hydrogen atom or an aliphatic radical, with the further limitation that at least one of R₆ or R₇ must be different from hydrogen and the other must contain between 10 and 22 carbon atoms. So, on the one hand the claim states that one or both of R₆ and R₇ may be hydrogen, and on the other hand the claim requires that neither R₆ nor R₇ can be hydrogen. Such ambiguities, combined with the vast breadth of the claimed subject matter, make it difficult to determine what Applicant intends to be the invention. Nonetheless, the Examiner has attempted to fairly restrict the inventions as follows.

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This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-11 and 12-23, drawn to compounds of the general formula CA(R1)–Rep-R, wherein R is lipidic, and wherein R1 is lipidic.

Group 2, claim(s) 1-11 and 12-23, drawn to compounds of the general formula CA(R1)–Rep-R, wherein R is lipidic, and wherein R1 is hydrophilic.

Group 3, claim(s) 1-11 and 12-23, drawn to compounds of the general formula CA(R1)–Rep-R, wherein R is lipidic, and wherein R1 is amphiphilic.

Group 4, claim(s) 1-11 and 12-23, drawn to compounds of the general formula CA(R1)–Rep-R, wherein R is lipidic, and wherein R1 is absent.

Group 5, claim(s) 1-11 and 12-23, drawn to compounds of the general formula CA(R1)–Rep-R, wherein R is hydrophilic, and wherein R1 is lipidic.

Group 6, claim(s) 1-11 and 12-23, drawn to compounds of the general formula CA(R1)–Rep-R, wherein R is hydrophilic, and wherein R1 is hydrophilic.

Group 7, claim(s) 1-11 and 12-23, drawn to compounds of the general formula CA(R1)–Rep-R, wherein R is hydrophilic, and wherein R1 is amphiphilic.

Group 8, claim(s) 1-11 and 12-23, drawn to compounds of the general formula CA(R1)–Rep-R, wherein R is hydrophilic, and wherein R1 is absent.

Group 9, claim(s) 1-11 and 12-23, drawn to compounds of the general formula CA(R1)–Rep-R, wherein R is amphiphilic, and wherein R1 is lipidic.

Group 10, claim(s) 1-11 and 12-23, drawn to compounds of the general formula CA(R1)–Rep-R, wherein R is amphiphilic, and wherein R1 is hydrophilic.

Group 11, claim(s) 1-11 and 12-23, drawn to compounds of the general formula CA(R1)–Rep-R, wherein R is amphiphilic, and wherein R1 is amphiphilic.

Group 12, claim(s) 1-11 and 12-23, drawn to compounds of the general formula CA(R1)–Rep-R, wherein R is amphiphilic, and wherein R1 is absent.

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Groups 13-24, claim(s) 10 and 11, drawn to methods of using compounds of the general formula CA-Rep-R to manufacture a medicament for treating diseases, wherein groups 13-24 correspond to methods of using compounds of groups 1-12, respectively.

Should Applicant elect any of groups 1-12, claims 1-11 and 12-23 will be examined only to the extent that they are described by the elected group. Should Applicant elect any of groups 13-24, claims 24-28 will be examined only to the extent that they are described by the elected group.

The inventions listed as Groups 1-24 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions correspond to compositions, methods of making the compositions, and to methods of using the compositions. However, the compositions first set forth in claim 1 lack a special technical feature because they are of dissimilar structure and function. According to the Administrative Instructions under the PCT, when alternatives of chemical compounds are claimed, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) all alternatives have a common property or activity, and
- (B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or
- (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In the instant case, not all of the embraced compositions have a common property or activity. For example, the claims embrace compositions as set forth in claim 9, which are essentially lipidic in nature, while also embracing compounds which have no lipidic character at all, i.e. in which 'q' (page 79, line 14) is 0, and 'R' is NH₂.

The specification does not teach how to use such widely divergent compounds for the same purpose or function. Furthermore, no significant structural element is shared by all of the alternatives of the claimed genus. The only structural feature required to be in all of the compounds is a highly generalized heterocycle of from 6 to 9 members in which either of two ring atoms may be either C or N, and in which any of the ring atoms may be substituted with an R₁ group that may be hydrophilic, hydrophobic, or amphiphilic. Note that the Administrative Instructions under the PCT indicate that heterocyclic rings of variable substitution generally do not have unity of invention absent some teaching of equivalence in the prior art. See Examples Concerning Unity of Invention, e.g. examples 19 and 20. In this case, N atoms, C atoms, hydrophobic substituents, hydrophilic substituents, and amphiphilic substituents clearly lack equivalence in the art of nucleic acid delivery because hydrophobic groups are generally involved in membrane permeabilization whereas hydrophilic groups are more generally involved in nucleic acid binding. N atoms may be positively charged and thereby involved in nucleic acid binding, whereas C atoms generally are not involved in nucleic acid binding. Finally, as noted above, the compounds do not all belong to a

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recognized class of chemical compounds, as some are lipidic, some are hydrophilic, and some are amphiphilic. Thus none of the criteria (A), (B)(1), or (B)(2) set forth in the Administrative Instructions under the PCT is met.

Because the compounds set forth in claim 1 lack a special technical feature, Applicant is not entitled to a grouping of separate categories of invention, i.e. methods of making and methods of using a composition are properly restricted from the compositions themselves. See 37 CFR 1.475 (a) and (b).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.



DAVE T. NGUYEN
PRIMARY EXAMINER